



OP- 3737
BET
11.1.99
#61 IDS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Mark R. Prausnitz, Jin Liu, and Thomas N. Lewis

RECEIVED

Serial No.: 09/229,226

Art Unit: 3737

OCT 21 1999

Filed: January 12, 1999

Examiner: Not Yet Assigned

Group 3700

For: *ASSESSMENT AND CONTROL OF ACOUSTIC TISSUE EFFECTS*

Assistant Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including four (4) pages of Form PTO-1449, a copy of each document cited therein, and a copy of the International Search Report mailed April 15, 1999, in PCT/US99/00659, which corresponds to the above-identified application.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It therefore is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 01-2507. A duplicate of this transmittal is enclosed to facilitate the process.

U.S. Patents

<u>Number</u>	<u>Issue Date</u>	<u>Patentee</u>	<u>Class/Subclass</u>
5,445,611	08-29-1995	Eppstein, et al.	604/49
5,636,632	06-10-1997	Bommannan, et al.	128/632
5,656,016	08-12-1997	Ogden	601/2

Publications

BAO, et al., "Transfection of a reporter plasmid into cultured cells by sonoporation in vitro," *Ultrasound Med. Biol.* 23:953-59 (1997).

BARNETT, et al., "Current status of research on biophysical effects of ultrasound," *Ultrasound Med. Biol.* 20: 205-18 (1994).

BRAYMAN, et al., "Hemolysis of albumex-supplemented, 40% hematocrit human erythrocytes in vitro by 1-MHz pulsed ultrasound: acoustic pressure and pulse length dependence," *Ultrasound Med. Biol.* 22:927-38 (1996).

CIARAVINO, et al., "Pulsed Enhancement of acoustic cavitation: a postulated model," *Ultrasound Med. Biol.* 7:159-66 (1981).

COLEMAN & SAUNDERS, "A review of the physical properties and biological effects of the high amplitude acoustic field used in extracorporeal lithotripsy," *Ultrasonics* 31:75-89 (1993).

EVERBACH, et al., "Correlation of ultrasound-induced hemolysis with cavitation detector output in vitro," *Ultrasound Med. Biol.* 23:619-24 (1997).

Exposure Criteria for Medical Diagnostic Ultrasound: I. Criteria Based on Thermal Mechanisms (NCRP Report No. 113), National Council on Radiation Protection and Measurements (Bethesda, MD 1992).

FECHHEIMER, et al., "Transfection of mammalian cells with plasmid DNA by scrape loading and sonication loading," *Proc. Natl. Acad. Sci. USA* 84:8463-67 (1987).

GAMBIHLER, et al., "Permeabilization of the plasma membrane of L1210 mouse leukemia cells using lithotripter shock waves," *J. Membr. Biol.* 141:267-79 (1994).

HOLMES, et al., "Altered neutrophil permeability following shock wave exposure in vitro," *J. Urol.* 147:733-37 (1992).

JEFFERS, et al., "Dimethylformamide as an enhancer of cavitation-induced cell lysis in vitro," *J. Acoust. Soc. Am.* 97:669-76 (1995).

KIM, et al., "Ultrasound-mediated transfection of mammalian cells," *Human Gene Ther.* 7:1339-46 (1996).

KIMURA, et al., "Standardization of ultrasonic power for sonochemical reaction," *Ultrasonics Sonochem.* 3:S157-S161 (1996).

KOBER, et al., "Effect of the pulse length of ultrasound on cell membrane damage *in vitro*," *J. Acoust. Soc. Am.* 86:6-7 (1989).

KOST & LANGER, "Ultrasound-mediated transdermal drug delivery" in Topical Drug Bioavailability, Bioequivalence, and Penetration (Shah & Maibach (eds.), pp. 91-104 (Plenum Press, New York 1993).

LEIGHTON, The Acoustic Bubble (Academic Press, London 1994).

MARGULIS, "Kinetics of the number of cavitation bubbles in an ultrasonic field," *Sov. Phys. Acoust.* 22:145-47 (1976).

MATULA, et al., "The acoustic emissions from single-bubble sonoluminescence," *J. Acoust. Soc. Am.* 103:1377-82 (1998).

MITRAGOTRI, et al., "Ultrasound-Mediated Transdermal Protein Delivery," *Science* 269:850-53 (1995).

MITRAGOTRI, et al., "Transdermal drug delivery using low-frequency sonophoresis," *Pharm. Res.* 13:411-20 (1996).

PRAUSNITZ, "Transdermal delivery of macromolecules: recent advances by modification of skin's barrier properties" in Therapeutic Protein and Peptide Formulation and Delivery (Shahrokh, et al., eds.) pp. 124-53 (American Chemical Society, Washington, DC 1997).

SAAD & HAHN, "Ultrasound-enhanced effects of adriamycin against murine tumors," *Ultrasound Med. Biol.* 18:715-23 (1992).

STEWART & STRATMEYER, eds., An Overview of Ultrasound: Theory, Measurement, Medical Applications, and Biological Effects (FDA 82-8190) (U.S. Department of Health and Human Services, Rockville, MD 1983).

SUSLICK, ed., Ultrasound: Its Chemical, Physical, and Biological Effects (VCH, Deerfield Beach, FL 1988).

TACHIBANA, et al., "Enhancement of cell killing of HL-60 cells by ultrasound in the presence of the photosensitizing drug Photofrin II," *Cancer Lett.* 72(3):195-199 (1993).

TACHIBANA & TACHIBANA, "Albumin microbubble echo-contrast material as an enhancer for ultrasound accelerated thrombolysis," *Circulation* 92(5):1148-50 (1995)

WILLIAMS, "A possible alteration in the permeability of ascites cell membranes after exposure to acoustic microstreaming," *J. Cell Sci.* 12:875-85 (1973).

U.S.S.N.: 09/229,226
Filed: January 12, 1999
INFORMATION DISCLOSURE STATEMENT

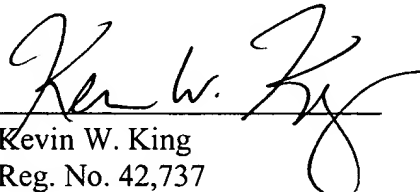
WYBER, et al., "The use of sonication for the efficient delivery of plasmid DNA into cells," *Pharm. Res.* 14:750-56 (1997).

ZHANG, et al., "Efficient transformation of tobacco by ultrasonication," *Biotechnology* 9:996-97 (1991).

Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,


Kevin W. King
Reg. No. 42,737

Dated: October 14, 1999

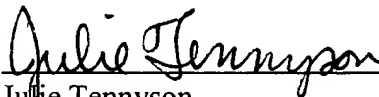
ARNALL GOLDEN & GREGORY, LLP
2800 One Atlantic Center
1201 W. Peachtree Street
Atlanta, Georgia 30309-3450
(404) 873-8596
(404) 873-8597 (fax)

U.S.S.N.: 09/229,226
Filed: January 12, 1999
INFORMATION DISCLOSURE STATEMENT

Certificate of Mailing under 37 C.F.R. § 1.8(a)

I hereby certify that this Information Disclosure Statement, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date shown below with sufficient postage as first-class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Date: October 14, 1999


Julie Tennyson

Please type a plus sign (+) inside this box →

+

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known	
		Application Number	09/229,226
		Filing Date	January 12, 1999
		First Named Inventor	Mark R. Prauznitz
		Group Art Unit	3737
		Examiner Name	
Sheet	1 of 4	Attorney Docket Number	GTRC1957

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	US Patent Document		Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
		5,445,611		Eppstein, et al.	08-29-1995	
		5,636,632		Bommannan, et al.	06-10-1997	
		5,656,016		Ogden	08-12-1997	

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM- DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office. ³	Number ⁴	Kind Code ⁵ (if known)				

Examine Signature	Date Considered
----------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.

Please type a plus sign (+) inside this box →

+

PTO/SB/08A (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
				Application Number	
				09/229,226	
				Filing Date	
				January 12, 1999	
				First Named Inventor	
Mark R. Prauznitz					
Group Art Unit					
3737					
Examiner Name					
Attorney Docket Number					
GTRC1957					

Sheet	2	of	4
-------	---	----	---

OTHER ART – NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		BAO, et al., "Transfection of a reporter plasmid into cultured cells by sonoporation in vitro," <i>Ultrasound Med. Biol.</i> 23:953-59 (1997).	
		BARNETT, et al., "Current status of research on biophysical effects of ultrasound," <i>Ultrasound Med. Biol.</i> 20: 205-18 (1994).	
		BRAYMAN, et al., "Hemolysis of albumex-supplemented, 40% hematocrit human erythrocytes in vitro by 1-MHz pulsed ultrasound: acoustic pressure and pulse length dependence," <i>Ultrasound Med. Biol.</i> 22:927-38 (1996).	
		CIARAVINO, et al., "Pulsed Enhancement of acoustic cavitation: a postulated model," <i>Ultrasound Med. Biol.</i> 7:159-66 (1981).	
		COLEMAN & SAUNDERS, "A review of the physical properties and biological effects of the high amplitude acoustic field used in extracorporeal lithotripsy," <i>Ultrasonics</i> 31:75-89 (1993).	
		EVERBACH, et al., "Correlation of ultrasound-induced hemolysis with cavitation detector output in vitro," <i>Ultrasound Med. Biol.</i> 23:619-24 (1997).	
		<i>Exposure Criteria for Medical Diagnostic Ultrasound: I. Criteria Based on Thermal Mechanisms (NCRP Report No. 113)</i> , National Council on Radiation Protection and Measurements (Bethesda, MD 1992).	
		FECHHEIMER, et al., "Transfection of mammalian cells with plasmid DNA by scrape loading and sonication loading," <i>Proc. Natl. Acad. Sci. USA</i> 84:8463-67 (1987).	
		GAMBIHLER, et al., "Permeabilization of the plasma membrane of L1210 mouse leukemia cells using lithotripter shock waves," <i>J. Membr. Biol.</i> 141:267-79 (1994).	
		HOLMES, et al., "Altered neutrophil permeability following shock wave exposure in vitro," <i>J. Urol.</i> 147:733-37 (1992).	

Examiner's Signature		Date Considered	
-------------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box →



PTO/SB/08A (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

+

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known	
		Application Number	09/229,226
		Filing Date	January 12, 1999
		First Named Inventor	Mark R. Praunzitz
		Group Art Unit	3737
		Examiner Name	
Sheet 3 of 4	Attorney Docket Number	GTRC1957	

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		JEFFERS, et al., "Dimethylformamide as an enhancer of cavitation-induced cell lysis in vitro," <i>J. Acoust. Soc. Am.</i> 97:669-76 (1995).	
		KIM, et al., "Ultrasound-mediated transfection of mammalian cells," <i>Human Gene Ther.</i> 7:1339-46 (1996).	
		KIMURA, et al., "Standardization of ultrasonic power for sonochemical reaction," <i>Ultrasonics Sonochem.</i> 3:S157-S161 (1996).	
		KOBER, et al., "Effect of the pulse length of ultrasound on cell membrane damage in vitro," <i>J. Acoust. Soc. Am.</i> 86:6-7 (1989).	
		KOST & LANGER, "Ultrasound-mediated transdermal drug delivery" in <u>Topical Drug Bioavailability, Bioequivalence, and Penetration</u> (Shah & Maibach (eds.), pp. 91-104 (Plenum Press, New York 1993).	
		LEIGHTON, <u>The Acoustic Bubble</u> (Academic Press, London 1994).	
		MARGULIS, "Kinetics of the number of cavitation bubbles in an ultrasonic field," <i>Sov. Phys. Acoust.</i> 22:145-47 (1976).	
		MATULA, et al., "The acoustic emissions from single-bubble sonoluminescence," <i>J. Acoust. Soc. Am.</i> 103:1377-82 (1998).	
		MITRAGOTRI, et al., "Transdermal drug delivery using low-frequency sonophoresis," <i>Pharm. Res.</i> 13:411-20 (1996).	
		MITRAGOTRI, et al., "Ultrasound-Mediated Transdermal Protein Delivery," <i>Science</i> 269:850-53 (1995).	

Examiner's Signature		Date Considered	
----------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

+

Please type a plus sign (+) inside this box →



PTO/SB/08A (10-96)
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

+

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	09/229,226
		Filing Date	January 12, 1999
		First Named Inventor	Mark R. Prauznitz
		Group Art Unit	3737
		Examiner Name	
Sheet 4 of 4	Attorney Docket Number	GTRC1957	

OTHER ART – NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		PRAUSNITZ, "Transdermal delivery of macromolecules: recent advances by modification of skin's barrier properties" in <u>Therapeutic Protein and Peptide Formulation and Delivery</u> (Shahrokh, et al., eds.) pp. 124-53 (American Chemical Society, Washington, DC 1997).	
		SAAD & HAHN, "Ultrasound-enhanced effects of adriamycin against murine tumors," <i>Ultrasound Med. Biol.</i> 18:715-23 (1992).	
		STEWART & STRATMEYER, eds., <u>An Overview of Ultrasound: Theory, Measurement, Medical Applications, and Biological Effects (FDA 82-8190)</u> (U.S. Department of Health and Human Services, Rockville, MD 1983).	
		SUSLICK, ed., <u>Ultrasound: Its Chemical, Physical, and Biological Effects</u> (VCH, Deerfield Beach, FL 1988).	
		TACHIBANA & TACHIBANA, "Albumin microbubble echo-contrast material as an enhancer for ultrasound accelerated thrombolysis," <i>Circulation</i> 92(5):1148-50 (1995)	
		TACHIBANA, et al., "Enhancement of cell killing of HL-60 cells by ultrasound in the presence of the photosensitizing drug Photofrin II," <i>Cancer Lett.</i> 72(3):195-199 (1993).	
		WILLIAMS, "A possible alteration in the permeability of ascites cell membranes after exposure to acoustic microstreaming," <i>J. Cell Sci.</i> 12:875-85 (1973).	
		WYBER, et al., "The use of sonication for the efficient delivery of plasmid DNA into cells," <i>Pharm. Res.</i> 14:750-56 (1997).	
		ZHANG, et al., "Efficient transformation of tobacco by ultrasonication," <i>Biotechnology</i> 9:996-97 (1991).	

Examiner's Signature	Date Considered
----------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

+